[CHAPTER 4]

Continuous Evaluation and Reevaluation

California law (Food and Agricultural Code 12824) requires DPR to "eliminate from use in the state" any pesticide that "endangers the agricultural or nonagricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented." To perform this function, the law requires the Department to "develop an orderly program for the continuous evaluation" of currently registered pesticides.

The principle that chemical use should not cause unacceptable risks to human health or the environment guides all DPR decisions. Before any pesticide is registered for use in California, DPR evaluates the pesticide's toxic potential, its potential exposure to people and the relationship between toxic effects and that potential exposure, and the potential for a pesticide to cause environmental problems. After a pesticide is registered, several DPR programs evaluate use practices to detect possible problems. For example, the Pesticide Illness Surveillance Program *(see Chapter 9)* identifies high-risk situations warranting DPR action to implement additional California restrictions on pesticide use. DPR conducts field studies to monitor exposure to workers and measure how pesticides move and break down in air, soil, and water. The Department uses the data collected to evaluate the effectiveness of DPR's regulatory programs and to assess the need for changes. Risk assessments completed on currently registered active ingredients may also trigger changes in DPR requirements on how a pesticide is used. Registrants are also required by law to report to DPR any adverse effects (for example, harm to humans, animals, or the environment) that occur after their products are registered.

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The Reevaluation Process

In addition, DPR has a formal Reevaluation Program. California regulations (Title 3, CCR Section 6221) require DPR to investigate all reports of actual or potentially significant adverse effects to people or the environment resulting from the use of pesticides. *(See Chapter 9 for a discussion of incident investigation.)* If DPR has reason to believe that a pesticide may cause unreasonable adverse effects to people or the environment, the regulations require DPR to reevaluate the pesticide to determine if it should remain registered.

The regulations specify factors that may initiate reevaluation. They include: (1) public or worker health hazard; (2) fish or wildlife hazard; (3) other information suggesting a significant adverse risk; (4) environmental contamination; (5) unwanted damage to plants; (6) residues over allowable limits; (7) hazardous packaging; (8) inadequate labeling; (9) lack of efficacy; (10) disruption of the implementation or conduct of pest management; or (11) availability of an effective and feasible alternative material or procedure which is demonstrably less destructive to the environment. Reevaluation is often triggered by ongoing Departmental registration reviews, State and county pesticide use surveillance and illness investigations, pesticide residue sample analyses, or environmental monitoring activities. Information from other State or federal agencies, or other sources, may also trigger a reevaluation.

The Pesticide Registration Branch administers the reevaluation process and coordinates data reviews and communication with registrants. When a pesticide enters the reevaluation process, DPR reviews existing data. DPR also requires registrants to provide additional data to determine the nature or the extent of the potential hazard or identify appropriate mitigation measures, if needed.

Legislation (Chapter 483, Statutes of 1997, SB 603) gave DPR the authority to cancel the registration of, or refuse to register, any pesticide if the registrant fails to

submit data requested in a reevaluation. If DPR cancels a registration, the registrant may request a hearing.

Data submitted by registrants are evaluated by the appropriate scientists or specialists in the Pesticide Registration, Medical Toxicology, Worker Health and Safety, Environmental Monitoring, Pest Management and Licensing, and Pesticide Enforcement Branches.

DPR concludes reevaluations in several ways. If the data show that use of the pesticide presents no significant adverse effects, DPR concludes the reevaluation without additional mitigation measures. If additional mitigation measures are necessary, DPR adopts regulations to mitigate the potential adverse effect. In applicable situations, DPR works with registrants and the U.S. EPA to revise labels to mitigate hazards. If the adverse impact cannot be mitigated, DPR cancels or suspends the registration of the pesticide product.

CCR Section 6225 regulations require DPR to prepare a semiannual report describing pesticides evaluated, under reevaluation, or for which factual or scientific information was received, but no reevaluation was initiated.

The U.S. EPA administers a program called Special Review that parallels DPR's reevaluation process. However, California's process deals with a broader range of issues that may affect only certain products rather than all products containing an active ingredient, and focuses on conditions peculiar to California use. U.S. EPA's Special Review, on the other hand, addresses risks posed by pesticide use on a national scale.

Registration...is not a recommendation of a product, for the Department does not endorse any product. Registration is simply a guarantee that the product is under supervision of the Department...
– 1933 Department annual report

Evaluating Pesticides in Air

DPR conducts air monitoring and evaluation under its general reevaluation mandate and under the mandates of Assembly Bill 1807 (Chapter 1047, Statutes of 1983, and amended by Chapter 1380, Statutes of 1984, AB 3219), the Toxic Air Contaminant Act.

Toxic Air Contaminant (TAC) Program: DPR's TAC program is one of several options the Department can use to control airborne pesticide residues. DPR has broad authority over the registration, sale, and use of pesticides in California to protect health and the environment. This authority is derived from a number of laws that cover all aspects of pesticide use in all media — air, ground and surface water, food, and in occupational and home-and-garden settings. This general regulatory authority allows DPR wide latitude to regulate application rates, ensure pesticide efficacy, designate pesticides as restricted materials, develop criteria to prevent unacceptable pesticide residues in food and water, license applicators and dealers, protect workers and finally to require reporting of all agricultural pesticide use. This authority is such that the Department can, with sufficient reason, demand that all use of a chemical cease immediately. Well before the 1983 passage of the TAC legislation, the Department regulated pesticides in air, beginning in the 1940s with regulations that governed maximum wind speeds and direction at time of application, and outlawing applications where conditions favored drift.

With the enactment of California's TAC legislation, the Legislature created the statutory framework for the evaluation and control of chemicals as toxic air contaminants. The statute defines TACs as air pollutants that may cause or contribute to increases in serious illness or death, or that may pose a present or potential hazard to human health. The law also requires listing as TACs all identified hazardous air pollutants (HAPs) under Section 7412 of Title 42 of the United States Code. DPR is responsible for the evaluation of pesticides as TACs. (The Air Resources Board [ARB] is lead agency for nonpesticidal substances in air.)

In general, the law focuses on the evaluation and control of pollutants in ambient community air. In implementing the law, DPR must conduct a review of the physical properties, environmental fate and human health effects of the candidate pesticide; determine the levels of the pesticide in air; and estimate human exposure and the potential human health risk from those exposures. The law requires DPR to list in regulation those pesticides that meet the criteria to be TACs. DPR must then determine the appropriate degree of control measures for the pesticide. Under its general regulatory authority, DPR may also conduct compliance monitoring to assure that users adhere to the control measures as appropriate.

DPR's TAC Program consists of two phases: risk assessment (evaluation and identification) and risk management (control). The first phase involves an extensive evaluation of the candidate pesticide to assess the potential adverse health effects and to estimate levels of exposure associated with its use. Environmental Monitoring Branch first prioritizes pesticides for consideration, placing them on a TAC candidate list based on the amount of pesticide used and sold in California, persistence in the atmosphere, and health effects information. DPR then requests the ARB to conduct California-specific monitoring studies to measure the air concentrations of pesticides. Different strategies must be used to monitor levels of pesticides in ambient air compared to other types of air pollutants, such as automobile exhaust. Because most of California's pesticide applications normally occur in agricultural areas and are seasonal in nature, ARB conducts the monitoring studies to collect data during the worst-case situation in the areas of high use during the season of peak use instead of collecting samples throughout the State. With the assistance of computer models, this "worst-case" information is later extrapolated to other locations and other times to estimate the ambient exposures of those people living near places where pesticides are used.

In general, for each candidate pesticide, two types of monitoring are conducted: samples are collected in ambient community air, and others in air near an application. For ambient community air measurements, ARB collects samples at three to five locations (usually schools or other public buildings) in communities near agricultural areas expected to receive applications of the pesticide being monitored. Samples of 24 hours in duration are collected for four days per week, for four or more consecutive weeks. For application-site monitoring (i.e., sampling before and after a specific application), samples are collected immediately before, during and for approximately 72 hours following a pesticide application.

To complete its evaluation, DPR is required to prepare a report for each pesticide that includes an assessment of exposure of the public to ambient concentrations of the pesticide; a risk assessment that includes data on health effects, including potency, mode of action, and other biological factors; an overview of the environmental fate and use of the pesticide; and the results of air monitoring studies conducted in California to measure the levels of the candidate pesticide present in ambient air. The draft report is peer-reviewed by OEHHA and the ARB. DPR subjects the document to public review through a workshop and comment period. Based on the results of these reviews, the draft report is revised as appropriate. The draft undergoes a rigorous peer review for scientific soundness by the TAC Scientific Review Panel (SRP), a panel of experts representing a range of scientific disciplines. As part of its review, the SRP prepares findings on whether the document considered all scientific information and recommends to DPR whether to list the pesticide as a TAC. Based on the results of this comprehensive evaluation, DPR determines whether the pesticide meets the criteria to be a TAC, and if so, regulations are adopted adding the pesticide to the TAC list.

Once a candidate pesticide has been declared a TAC, it enters phase two of the program: the mitigation, or control, phase. In the mitigation phase, DPR investigates the need for and appropriate degree of controls for the TAC. If reductions in exposure are needed, DPR must develop control measures to reduce emissions to levels that adequately protect public health. DPR must use the best practicable control techniques available, which may include, but are not limited to, changing the use instructions on the product label; applicator training; restrictions on use patterns or locations; changes in application procedures; reclassification of the pesticide as a restricted material; or banning use by canceling a product's registration. In developing control measures, the law requires DPR to coordinate with the County Agricultural Commissioners, air pollution control districts, and air quality management districts in the counties where the pesticide is used.

From late 1998 through 2000, DPR made several changes to its AB 1807 implementation policies and procedures to fully integrate the TAC process into its ongoing review and assessment of pesticides. Working with the SRP, the Department merged its comprehensive risk assessment procedures to conform with established AB1807 procedures. DPR scientists undertook internal steps to ensure that the presentations of their scientific assessments were made in a manner consistent with other AB 1807 documents. This effort resulted in a consistent presentation of scientific assessments from DPR and OEHHA.

Without intensive legal and chemical control of these highly technical products, unscrupulous persons could exploit consumers, and deliver deficient, hazardous, or fraudulent materials.
– 1944 Department annual report

The use of airplanes in the application of insecticides has received considerable impetus during recent years...
– 1934 Department annual report

Working with the SRP, the Department also established a mechanism to ensure that the priorities set for TAC monitoring reflected the Department's overall priority list for conducting risk assessments (under the Birth Defect Prevention Act and as part of the registration process). Differences between the priority list for TAC candidate monitoring and the risk assessment priority list led to monitoring being done many years before a risk assessment was completed. As a result, some monitoring studies were 10 or more years old by the time the rest of a submittal was ready for the SRP. In the interim, use patterns may have changed, making the monitoring data less relevant.

Moreover, DPR made changes in its overall risk characterization process to ensure that the toxicological evaluations done under other programs could be readily used as the basis of required TAC documents. The Department also made changes to ensure transparency of the TAC process, posting draft reports on its Web site and accepting comments via E-mail in addition to the normal comment process. The Department also worked with the SRP to establish a timetable for regular submission of health effects documents to the Panel for its review and findings as a precursor to possible regulatory listing as a TAC. The goal is more efficient monitoring strategies and activities, and streamlined mitigation activities.

Other Air Programs

Separate from the formalized TAC and volatile organic compound (VOC) programs *(see Chapter 11 for discussion of VOC program)*, DPR also conducts air monitoring as part of its continuing evaluation of pesticides. Environmental Monitoring Branch characterizes the source and recommends mitigation measures for off-target movement of pesticide residues that have resulted in crop damage, illegal crop residues, contamination of the environment, or complaints by the public. The Registration Branch may use this information in reevaluating the use of currently registered pesticides. The Enforcement Branch also uses the data in developing restricted materials permit conditions and use regulations designed to mitigate problems caused by pesticides in air. These monitoring studies help DPR evaluate the likelihood of pesticides causing health problems for workers using pesticides and for people near treated areas, and to provide data to develop new use practices designed to prevent harm. However, even the most carefully developed risk reduction measures cannot adequately take into account the variety of situations that occur in nature; various microclimates and special environmental characteristics can produce unexpected results. Therefore, DPR periodically does monitoring to evaluate the effectiveness of its risk reduction measures. If air monitoring finds unacceptable levels of pesticides in ambient air, monitoring data helps in the development of new control measures. For example, in 1997 and 1998, DPR conducted extensive monitoring of methyl bromide field fumigations to validate the effectiveness of the restrictions on the widely used fumigant. As a result, new suggested permit conditions were issued in November 1997, increasing the size of the minimum buffer zones. In 1998, again based on monitoring and other data, DPR reduced the minimum buffer zones for some fumigations of less than 10 acres. In 2000, based on extensive monitoring studies and other data, the Department adopted regulations formalizing many use restrictions carried out earlier by permit condition.

Environmental Monitoring Branch analyzes air monitoring data to assist the Medical Toxicology and Worker Health and Safety Branches in conducting risk characterizations, and monitors air residues of pesticides applied by the California Department of Food and Agriculture to eradicate exotic pests (such as the Mediterranean fruit fly). This information is used to help assure that the public is not exposed to levels of pesticides that may cause adverse health effects. Environmental Monitoring Branch also conducts special projects targeted at specific regional concerns. For example, in 1999 and 2000, DPR conducted monitoring for fumigants and other agricultural pesticides used around Lompoc in Santa Barbara County, to help resolve community concerns about possible overexposure to pesticides and resulting health problems. *(See Chapter 13 for discussion of Lompoc Interagency Work Group activities.)*